

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: WHITE, JAMES M.

SERIAL NO.: 09/596,370

ART UNIT: 1744

FILED: June 19, 2000

EXAMINER: CHARBAJI, M.R.

TITLE: BIOLOGICAL FLUID DISPOSAL SYSTEM

AMENDMENT "A"

Director of the U.S. Patent  
and Trademark Office  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In response to the Office Action of December 8, 2003, having a response being due by March 8, 2004, please consider the following remarks:

REMARKS

Upon entry of the present remarks, previous Claims 1 - 20 have been canceled and new Claims 21 - 35 substituted therefor. Reconsideration of the rejections, in light of the forgoing amendments present remarks, is respectfully requested. The present amendments have been entered for the purpose of distinguishing the present invention from the prior art.

In the Office Action, it is indicated that Claims 1 - 2, 4 - 5, 8 - 10, 12 - 13, 17 - 18 and 20 were rejected under 35 U.S.C. § 102(b) as anticipated by the Saunier patent. Claims 3 and 14 were rejected under 35 U.S.C. § 103(a) as being obvious over the Saunier patent in view of the Jackson patent. Claims 6 - 7, 15 - 16 and 19 were rejected under 35 U.S.C. § 103(a) as being obvious over

the Saunier patent in view of the Griffiths patent. Claim 11 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the Saunier patent in view of the Aubrey patent. Additionally, Claims 12 and 17 - 18 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claim 17 was rejected because of a lack of antecedent basis.

As an overview to the present reply, Applicant has canceled previous Claims 1 - 20 and substituted Claims 21 - 35 therefor. In particular, independent Claim 21 incorporates the limitations of previous dependent Claim 11 pertaining to the "housing". It is further indicated in independent Claim 21 that the water flow line has an inlet and an outlet extending outwardly of the housing. The biological fluid line also is indicated as having an inlet positioned outwardly of the housing. The disinfectant line is also indicated as having an inlet extending outwardly of the housing. Independent Claim 21 further recites that the disinfectant line is in "valveless" fluid communication with the biological fluid line. Independent Claim 21 also indicates that only the flow of water through the water flow line causes the suction action through the biological fluid line and the disinfectant line so as to "draw a biological fluid through the biological fluid line and draw a disinfectant through the disinfectant line so as to mix the disinfectant with the biological fluid prior to passing into the water flow line". The housing is indicated as having "no pumps" therein.

New independent Claim 29 incorporates the limitations of previous independent Claim 12 and the limitations of dependent Claim 16. The "venturi means" causes the suction force which draws the "biological fluid through the biological fluid line and draws the disinfectant through the disinfectant line so as to mix intimately together in the biological fluid line prior to passing as a mixture into the water flow line". Independent Claim 29 also indicates that the biological fluid is substantially blood.

Independent Claim 33, the method claim, indicates that the biological fluid line is connected "in valveless relation" to the disinfectant line. Independent Claim 33 indicates that it is the water flow which "solely" draws the biological fluid and the disinfectant through their respective lines. Independent Claim 33 also indicates that the biological fluid is "substantially blood".

Applicant respectfully contends that the features amended into independent Claims 21, 29 and 33 serve to clearly distinguish the present invention from the prior art combination.

It is important to note that the purpose of the present invention is to provide a convenient and easy unit to install in the hospital environment whereby a disinfectant can be mixed with blood prior to passing the biological fluid to the sewer. It was important to provide a system whereby no pumps or valves were required in order to create the proper mixture of disinfectant and blood. Additionally, in the system of the present invention, it is also important to create a system whereby, when the biological fluid and the biological fluid container was exhausted, no more disinfectant would be drawn into the system. The present invention utilizes a unique system of venturi effect, along with orifice relationships, so as to properly mix the components together. This structure is neither shown nor suggested in the prior art patents.

In particular, in the original specification, the difficulties of the prior art were recited on page 4, lines 4 - 11, as follows:

Unfortunately, these systems utilize complex arrangements of mechanical pumps for the purpose of mixing the disinfectant with the biological fluid. In many circumstances, the pump itself must be repaired or cleaned so as to make the system suitable for future use. The use of various mechanical and electrical pumps further complicates the system and makes the system much more expensive. It is often difficult to specifically and accurately regulate the mixture of fluid with the disinfectant using such systems. Whenever such mechanical and electrical systems are employed, repair is frequently

required. Under certain circumstances, the pumps and fluid lines must be primed before the pumping and mixing action can occur.

The use of the venturi effect is an important feature of the present invention for drawing the mixture of biological fluid and disinfectant together for the purposes of decontaminating the biological fluid.

This function was recited on pages 7 and 8 of the original specification as follows:

The flow of water through the water flow line 14 across the outlet 22 creates a venturi effect so as to create a suction within the pipe 20 for drawing the disinfectant 24 through the disinfectant line 18 and for drawing the biological fluid 26 into and through the biological fluid line 16.

As a result of the structure of the present invention, a static pumpless and generally valveless system is created. This eliminates a large part of the cost and difficulty associated with the prior art. As was stated on page 10, lines 4 - 12 of the original specification:

As can be seen in the present invention, the system 10 is a static system which does not require mechanical or electrical appliances. The venturi action of passing the flow of water across the outlet 22 will cause a proper mixing of the disinfectant 24 with the biological fluid 26. No complicated pumping mechanisms are required. The water inlet 28 can be simply connected to a source of water pressure. The outlet of the water flow line 14 can be simply inserted into a suitable drain so that the mixed and disinfected biological fluid can be discharged into a sewer. The arrangement of the components assures a proper mixture of disinfectant 24 and biological fluid 26 for decontamination. Cleaning of the system is very easy because of the lack of mechanical mechanisms.

Additionally, the present invention allows the proper mixing of biological fluid and disinfectant without the need for self-regulation. This feature was recited in the original specification on page 10, lines 13 - 17.

An interesting feature of the present invention is that the system is its self-regulation. In any venturi-type system, fluids will flow in the direction of least resistance. When the supply of biological

fluid 26 is exhausted from container 50, the inlet 32 will simply suck air therethrough. As a result, no disinfectant 24 will be drawn, at that time, from the container 58. As such, there is no need to monitor the system to shut off the system when the biological fluid supply is exhausted.

Applicant respectfully contends that the prior art patents, individually or in combination, fail to show the features the present invention as defined herein.

The prior art Saunier patent simply shows a process of sterilizing water by the combination of chlorine and another halogen. Generally, this is used for the disinfection or sterilization of drinking water, municipal waste, industrial waters or swimming pool waters. In this system, a reactor receives a mixture of chlorine and salt of another halogen. This is from a field of art far removed from the disinfection and disposal of medical waste or biological material. Applicant has recited in certain of the independent claims that the biological fluid is "substantially blood" so as to distinguish the present invention from the teachings of the Saunier patent. Applicant respectfully contends that a reasonable interpretation of the "biological fluid" would not include "raw water".

Fundamentally, the Saunier patent utilizes a series of pumps that are interconnected together, along with the use of valves, so as to establish the proper mixing relationship. In contrast, the present invention is "pumpless" system. The present invention relies upon the venturi effect so as to create the proper mixing. In particular, the Saunier patent requires an over-pressure pump 6, a valve 9 and a proportioning pump 2. The pumps must be set in relationship to each other so as to establish the proper relationship. As a result, each of the components can be mixed together within a reactor 1. The complicated arrangement of the Saunier device was described in column 3, lines 65 - 69, as follows:

The pump 6 carries out a mixing which facilitates the chlorine enrichment and, moreover, compensates the pressure drop in the circuit; the chlorine water therefor comes out under pressure through the pipe 8 and can feed the reactor 1 directly under pressure. The chlorine concentration and the flow are strictly controlled.

It is further indicated how the halide is injected into the chlorine water in column 4, lines 3 - 5, as follows:

The halide, e.g. the bromide is injected by means of the adjustable proportioning pump 2 from the storage tank 3.

Suitable valves are provided along the system to further ensure the proper mixing relationships.

The prior art Aubrey system is a very complicated mixing apparatus employing a variety of pumps and valves. In particular, the purpose of the Aubrey patent is simply for the mixing of x-ray processing chemicals. The Aubrey system utilizes a series of valves for the purpose of controlling mixing and for regulating the mixtures. The mixture is regulated through the use of a variety of different flow meters. Constant monitoring of the liquid mixing apparatus of the Aubrey patent is required so as to assure that the proper mixture is obtained.

The Jackson patent teaches an apparatus for the treatment and disposal of infectious waste. The Jackson patent is quite distinguishable from the present invention in that the Jackson patent is a timed batch process. The Jackson device requires the use of a macerator 26 for chopping the waste. Various assorted pumps are provide throughout the system so as to pump the waste into a container for holding in a batch. A variety of timers, pumps, and assorted controls are requires so as to assure that the disinfectant is contained within the waste for a desired period of time and in proper proportions.

The Griffiths patent describes a static mixing apparatus 76 for the purpose of mixing the biological fluid with the disinfectant. However, the biological fluid and the disinfectant are maintained in a mixed condition within a reservoir in a "batch process" type of system. A variety of pumps are employed throughout the system of the Griffiths patent so as to assure the proper delivery and mixture of the components. Similarly, several valves are integrated into the system so as to direct the flow of fluids from one direction or another. Pumps are required to discharge the waste from the reservoir outwardly to the sewer system.

Relative to the independent claims, as amended herein, Applicant respectfully contends that the combination of the Saunier and Aubrey patents would not teach the limitations of the independent Claim 21. Fundamentally, it is very difficult to see how the raw water treatment process of the Saunier patent can be combined, in any way, with the x-ray development component mixing system of the Aubrey patent. These are from entirely different fields of art, each of which is very unrelated from the field of biological fluid disposal. Although the Aubrey patent does teach a "housing", Applicant respectfully contends that there is no teaching in the combination of references that would suggest the use of the housing, as limited by independent Claim 21 in which the inlets to the water flow line, biological fluid line and the disinfectant line extend outwardly of the housing. The prior art combination fails to show that it is "solely" the flow of water through the water flow line which causes the suction action through which the biological fluid mixes with the disinfectant in the biological fluid line. The prior art combination would also disclose the use of pumps therein. This is contrary to the "no pumps" defined within the housing of independent Claim 21. There is no suggestion in this prior art combination of the "venturi effect" for the purposes of facilitating mixtures.

Relative to independent Claim 29 (incorporating the limitations of independent Claim 12 and 16), Applicant respectfully contends that the combination of the Saunier and Griffiths patents would fail to disclose the structure of the present invention as defined by independent Claim 29. Once again, Applicant's attorney finds it exceedingly difficult to see how the very complicated structure of the Griffiths patent can be combined, in any way, with the raw water disinfection system of the Saunier patent so as to show the biological fluid disposal system of the present invention. It is clear that only components of each of these systems are joined together for the purposes of "making obvious" the teachings of independent Claim 29. There would be no natural reason for combining these prior art teachings. Fundamentally, neither the Saunier patent nor the Griffiths patent discloses the use of "venturi effect" for creating the "suction force" for drawing the biological fluid through the biological fluid line and for drawing a disinfectant through the disinfectant line. There is nothing to indicate that the disinfectant mixes with the biological fluid in the biological fluid line prior to passing as a mixture into the water flow line. In fact, the use of pumps in the Griffiths patent and in the Saunier patent would teach against the use of any "suction force" created by the "venturi means" of the present invention. In neither of the Saunier or Griffiths patents does the water flow itself create the suction force. On this basis, Applicant contends that independent Claim 21 is not "obvious" in view of the prior art combination.

Relative to independent Claim 33, Applicant respectfully contends that this claim is not "anticipated" by the Saunier patent. Importantly, the Saunier patent, in no way, describes a system for treating a biological fluid which is "substantially blood". The Saunier patent, in no way, passes water through a water flow line across an outlet so as to "cause a venturi effect to solely draw a biological fluid and a disinfectant" through the respective biological fluid line and disinfectant line.



Additionally, and furthermore, the Saunier patent does not teach the "valveless relationship" between the biological fluid line and the disinfectant line. On this basis, Applicant contends that independent Claim 33 is not anticipated by the prior art Saunier patent.

Relative to the formality objections under 35 U.S.C. § 112, second paragraph, Applicant has revised the language pertaining to "a venturi means connected to one of said lines" to read that the venturi means is "connected to said water flow line". Relative to Claims 17 and 18, Applicant notes that it is possible, within another form of the present invention, that the disinfectant line can be directly connected to water line and that the biological fluid line can pass into the disinfectant line. The "outlet" is the outlet for one of these two lines. Applicant's attorney believes that the explanation for such a structure is clearly recited in the original specification.

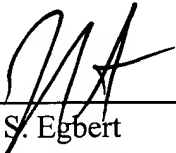
Relative to the dependent claims herein, dependent Claims 22 - 25 correspond, respectively, to original dependent Claims 2 - 5. Dependent Claims 26 - 28 correspond, respectively, to the limitations of previous dependent Claims 7 - 9. Dependent Claims 30 - 32 correspond, respectively, to the limitations of original dependent Claims 13 - 15. Dependent Claims 34 and 35 correspond, respectively, to the limitations of previous dependent Claims 18 and 19.

Based upon the foregoing analysis, Applicant contends that independent Claims 21, 29 and 33 are now in proper condition for allowance. Additionally, those claims which are dependent upon these independent claims should also be in condition for allowance. Reconsideration of the rejections

and allowance of the claims at an early date is earnestly solicited. Since no new claims have been added above those originally paid for, no additional fee is required.

Respectfully submitted,

2.25.04  
Date

  
\_\_\_\_\_  
John S. Egbert  
Reg. No. 30,627  
Andrew W. Chu,  
Reg. No. 46,625  
Attorney for Applicant  
Harrison & Egbert  
412 Main Street, 7<sup>th</sup> Floor  
Houston, Texas 77002  
(713)224-8080  
(713)223-4873 fax